EPA

MRID NUMBER

NR94340999

MRID: NR
94340999

A.H. ROBINS COMPANY
Regulatory Affairs and Product Development
Special Products Division
P. O. Box 27709
Richmond, VA 23261-6609
(804) 257-2035

April 29, 1992

Document Processing Desk
Office of Pesticide Programs
U.S. Environmental Protection Agency
Attention: Denise Greenway (H7508W)
401 M Street, S.W.
Washington, D.C. 20460

RE: Request for Meeting
Reregistration of Potassium Peroxymonosulfate (Case 4072, Chemical 63604)

Dear Ms. Greenway:

Following our review of data available to support continued registration of this compound for use as a pesticide, we feel that a meeting is most desirable to discuss several questions which may be unique to this compound and which will affect both how EPA/OPP evaluates the data submitted and determines which additional data may be required to be developed in the future. Among these questions are:

a) Is potassium peroxymonosulfate really a pesticide "active ingredient" as defined by FIFRA?

b) Since potassium peroxymonosulfate exists only as a "triple salt" rather than as a single salt (with the other two salts not listed as active ingredients), may any additional data required be developed only on the triple salt?

c) Since the pesticide effects claimed on the VIRKON-S label are produced by chemicals present in the water solution used to apply the treatments, which have changed from the chemicals present in the container which is packaged, labeled and released for shipment, should the time table for reregistration of the "active ingredients" listed on the VIRKON-S label be extended until EPA begins the process of reregistering end-use products?

1

It is the intent of the registrant, A.H. Robins, and the manufacturer, Antec International, Ltd., to comply with accelerated reregistration procedures mandated in the 1988 amendments to FIFRA. However, since the volume of VIRKON-S sold each year is not large, time and money must be spent wisely. We feel the meeting requested would be essential to outline a program for reregistration which is acceptable to all parties.

We request that a representative of the manufacturer of VIRKON-S, Antec International, Ltd., be allowed to contact you in mid-May 1992 to set a date for a meeting to discuss in detail the questions listed above. His name is Mr. Richard J. Otten (919-846-7860).

Sincerely,

Donald L. Gilbert

Donald L. Gilbert
Regulatory Affairs and Product Development
Special Products Division

New Topic

ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460
Reregistration Phase 2 Response Worksheet

PART 5
Page 1 of 20

1. Company Name	2. Case Number	3. Case Name
A.H.Robins Company	4072	
4. Chemical Name		**5. Chemical Number**
Potassium peroxymonosulfate		

Guideline Reference Number	Title of Study	Use Groups: terrestrial: food: feed crop	terrestrial: food: feed crop	terrestrial: non-food: non-food crop	aquatic: food: food crop	aquatic: non-food: outdoor	aquatic: non-food: industrial	aquatic: non-food: residential	greenhouse: food: food crop	greenhouse: non-food: non-food crop	forestry: forestry	residential outdoor	indoor: food: food	indoor: non-food: non-food	indoor: non-food: medical	indoor: non-food: residential	7 This data Req'mt applies to my chemical: YES	7: NO	8 How I will comply with this data requirement: 1	2	3	4	5	6	7	8	9	9 Time permitted for submission to EPA (in Years)
		6												X														
61-1	Chemical Identity	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
61-2(a)	Begin. mat. & manfg. proc	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
61-2(b)	Discussion of Impurities	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
62-1	Preliminary Analysis	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	X		X									1
62-2	Certification of limits	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
62-3	Analytical Method	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-2	Color	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-3	Physical State	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-4	Odor	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-5	Melting Point	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-6	Boiling Point	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-7	Density	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-8	Solubility	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X									1
63-9	Vapor Pressure	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R		X							X			1
63-10	Dissociation Constant	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R		X							X			1
63-11	Oct/Water partition Coef.	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR		X							X	-		1

11 Certification
I certify that the statements that I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative: Donald L. Gilbert

12 Date: February 28, 1992

13 Name of Company Contact: Donald L. Gilbert

14 phone number: 804-257-2000

Revision A 8-7-89

pin punch
date: 3/11/92

4

Form Approved. OMB No. 2070-0107. Approval Expires 9-30-90.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460
Reregistration Phase 2 Response Worksheet

PART B
Page 1 of 12

1. Company Name	ABIC, LTD.	2. Case Number	3059	3. Case Name	DICHLOROPHEN
4. Chemical Name	DICHLOROPHEN			5. Chemical Number	055001

Guideline Reference Number	Title of Study	Use Groups: terrestrial: food: food crop	terrestrial: food: feed crop	terrestrial: food: non-food crop	terrestrial: non-food: food crop	terrestrial: non-food: outdoor	terrestrial: non-food: industrial	terrestrial: non-food: residential	aquatic: food: food crop	aquatic: non-food: non-food crop	aquatic: non-food: forestry	aquatic: residential outdoor	greenhouse: food	greenhouse: non-food	forestry	residential outdoor	Indoor: food	Indoor: non-food	Indoor: medical	Indoor: residential	7 This data Req'mt applies to my chemical: YES	7: NO	8 How I will comply with this data requirement: 1	2	3	4	5	6	7	8	9	9 Time permitted for submission to EPA (in Years)
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62-1	Preliminary Analysis	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR		X	X								1
62-2	Certification of limits	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X					X					1
62-3	Analytical Method	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X		X								1
63-2	Color	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X					X					1
63-3	Physical State	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X					X					1
63-4	Odor	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X					X					1
63-5	Melting Point	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X					X					1
63-6	Boiling Point	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R		X							X			1
63-7	Density	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X					X					1
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63-9	Vapor Pressure	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	X					X					1
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Signature of Company's Authorized Representative: Peggy M. Galloway

12 Date 12/30/91

13 Name of Company Contact: Peggy M. Galloway, Regulatory Agent
LANDIS INTERNATIONAL, P.O. Box 5126, Valdosta, GA 31603-5126

14 phone number (912) 247-6472

Revision A 8-7-89.

CT

New Topic

A.H. ROBINS COMPANY
Regulatory Affairs and Product Development
Special Products Division
P. O. Box 26609
Richmond, VA 23261-6609
(804) 257-2035

April 29, 1992

Document Processing Desk
Office of Pesticide Programs
U.S. Environmental Protection Agency
Attention: Denise Greenway (H7[illegible]
401 M Street, S.W.
Washington, D.C. 20460

RE: Reregistration Phase 3 Chemical Response Worksheets
Potassium Peroxymonosulfate (Case 4072, Chemical 63604)

Dear Ms. Greenway:

As promised in our previous discussions and during your discussion with Mr. Richard Otten on April 24, 1992, we are submitting our revised Phase 3 Response Worksheets to replace the preliminary worksheets submitted on March 30, 1992. Summaries and actual data are being submitted also as noted in the Worksheet. This complies with EPA's due date of April 30, 1992, as expressed in Mr. Sidwell's letter to me of April 9, 1992.

Upon our review of the product chemistries and modes of actions involved and on Mr. Otten's discussion with you, it appears reregistration of this compound warrants special consideration. It may have been a misnomer to have previously identified this substance as an "active ingredient" for pesticidal purposes, as defined by FIFRA. Therefore, it is extremely difficult to force fit data on this compound into the format for reregistration as stated in EPA's Guidance Package for reregistration of conventional pesticide active ingredients.

A detailed discussion of our reasons are included in the attachment to our response worksheets. I will highlight a few:

(1) Potassium peroxymonosulfate does not exist as a separated entity; it must be present as a triple salt including other potassium sulfates to avoid immediate decomposition following manufacture.

(2) It may be the oxygen (O_2) formed when the triple salt is dissolved in water prior to treatment which produces most of the viricidal effect. But listing oxygen on the product label as the "active ingredient" is inconsistent also, since oxygen does not exist as O_2 in the registered pesticide product "packaged, labeled and released for shipment".

(3) Similarly, the ubiquitous compound, sodium chloride (common table salt), acts as a source for chlorine (Cl_2), a common biocide, produced after dissolving in water in the presence of the strong oxidizing agent, $KHSO_5$. Sodium chloride itself is not the active biocide.

However, in an effort to comply with the intent of EPA's reregistration requirements, and assuming for the time being that this compound will continue to be identified as a pesticide active ingredient, we have submitted summary product chemistry information on the triple salt of potassium peroxymonosulfate and have evaluated available acute toxicity data on this triple salt against EPA's Acceptance Criteria and have reformatted and summarized each study.

Also, the present manufacturer of the triple salt, Antec International, Ltd., has committed to us to develop such new data as may be required to reregister it within time frames provided in the Phase 3 Worksheet. You may already have been contacted by Mr. Richard J. Otten, who will be acting as a U.S. regulatory consultant to Antec on this program. Future questions on reregistration of these compounds should be directed to him (919-846-7860).

Sincerely,

Donald L. Gilbert
Regulatory Affairs and Product Development
Special Products Division

New Topic

TRANSMITTAL DOCUMENT

1. **Name and address of submitter:**

A.H. Robins Company
Regulatory Affairs and Product Development
Special Products Division
1407 Cummings Drive
P. O. Box 27709
Richmond, VA 23261-6609

2. **Regulatory action in support of which this package is submitted:**

Reregistration Phase 3 Response
Potassium Peroxymonosulfate
Case 4072, Chemical 63604

3. **Transmittal Date:**

April 29, 1992

4. **List of Submitted Studies:**

VOLUME 1:
ADMINISTRATIVE MATERIALS

- Letter to Ms. Greenway, Special Review & Reregistration Division
- Phase 3 Response Worksheet
- VIRKON-S Label Text, Guideline No. 171-3
- Discussion of potassium peroxymonosulfate; pesticide active ingredient or an activator of other pesticide compounds?
- Request for meeting to discuss classification as pesticide
- Request for waivers of other data

VOLUME 2:

- Product Chemistry Summary
(Guideline Studies 61, 62 and 63)

VOLUME 3:

- Data Sheet on OXONE® Monosulfate Compound
- Material Safety Data Sheet on OXONE® Monosulfate Compound

VOLUME 4:

Acute Toxicity Summary and Data Guideline Studies

COMPANY OFFICIAL: Donald L Gilbert MD
(signature)
Dr. Donald L. Gilbert
Regulatory Affairs and Product Development

COMPANY NAME: A.H. Robins Company

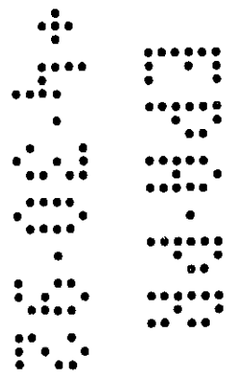
COMPANY CONTACT: Dr. Donald L. Gilbert Phone: (804) 257-2035

New Topic

Reregistration Phase 3 Response
Potassium Peroxymonosulfate

VOLUME 1

ADMINISTRATIVE MATERIALS



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A.H. ROBINS COMPANY
Regulatory Affairs and Product Development
Special Products Division
P. O. Box 26609
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April 29, 1992

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Sincerely,

Donald L. Gilbert

Donald L. Gilbert
Regulatory Affairs and Product Development
Special Products Division

LABEL TEXT

VIRKON® S Broad Spectrum Disinfectant

DATA REQUIREMENT

Guideline No. 171-3

DIRECTIONS FOR USE

EPA REG. NO. 778-91 - 63690

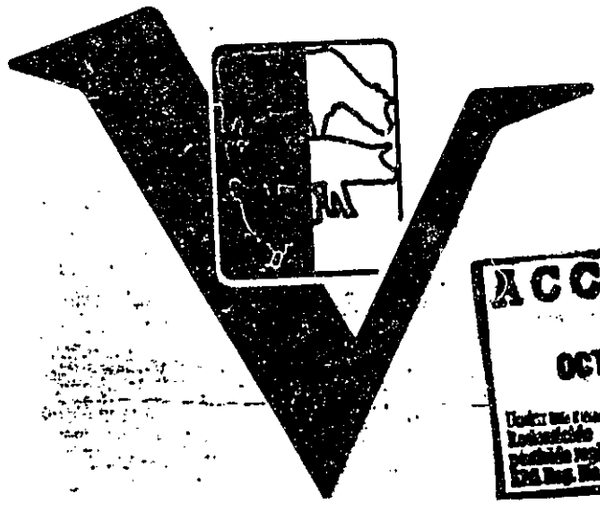
SOURCE

Agri-Bio Corp
a subsidiary of A.H. Robins Company

DATE

October 26, 1990

Antec International



VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease	Aspergillus flavus Aspergillus fumigatus Candida albicans
	Avian Leucoencephalitis Avian Influenza Marek's Disease	

Supplied as 4.79% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER

See Back Panel for Additional Precautionary Statements

1 Litre (5kg) Net Weight

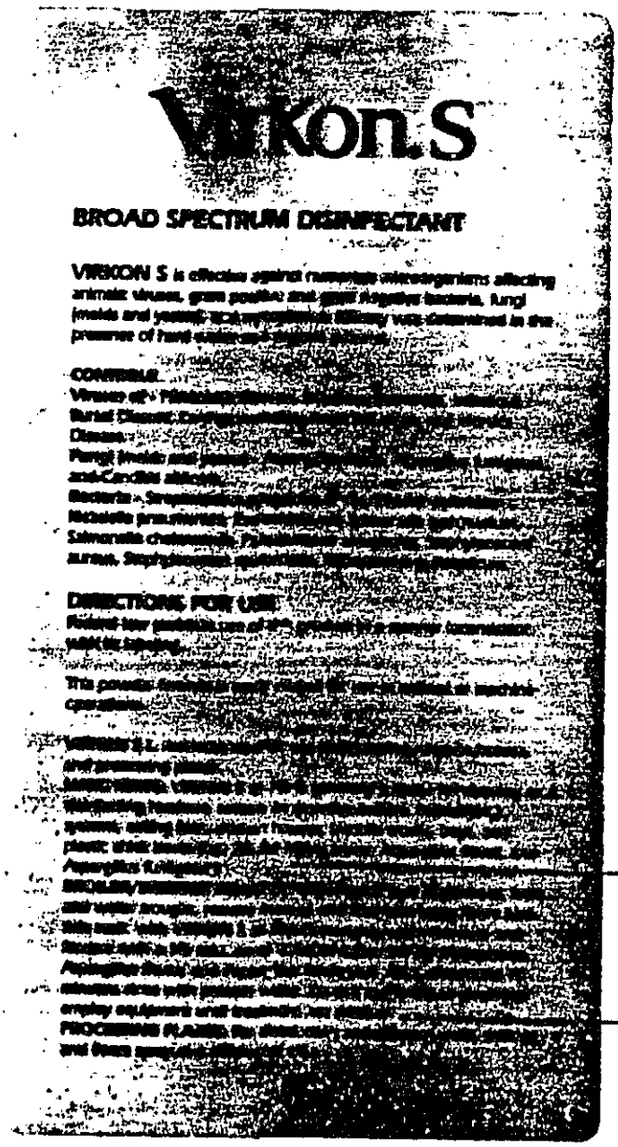
AGRI-BIO®

Agri-Bio Corp., a subsidiary of A.H. Robins Company
966 Dorsey St. Gainesville, GA 30501, phone 1-800-AGRI-BIO (247-4246)

In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512



Virkon S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts) and mycobacteria. Efficacy was determined in the presence of hard water and organic soil.

CONTROLS

DIRECTIONS FOR USE

Virkon S is recommendeded for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Virkon S at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers acccrding to manufacturer's use directions.

For air sanitizing: Virkon S at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

DISCUSSION OF POTASSIUM PEROXYMONOSULFATE; A Pesticide Active Ingredient Or An "Activator" Of Other Pesticide Products?

Following are reasons why potassium peroxymonosulfate does not fit into EPA/OPP's guidance for filing a Phase 3 Response for Reregistration as a pesticide active ingredient. See the February 25, 1992 letter from duPont and description of VIRKON-S from Antec International.

1) Potassium peroxymonosulfate ($KHSO_5$) does not exist as an isolated chemical. Therefore, Guideline 61, 62 and 63 data cannot be produced $KHSO_5$ per se.

2) Potassium peroxymonosulfate is not stable by itself It must be made into a "triple salt" with potassium sulfate and potassium hydrogen sulfate ($2KH2O_5 \cdot KHSO_4 \cdot K_2SO_4$) to be packaged and sold for pesticidal purposes.

3) Potassium peroxymonosulfate as the triple salt breaks down in the aqueous solution used to sanitize surfaces and releases oxygen, which may be the more potent viricide. Minimum oxygen equivalent content of the triple salt is stated at 4.5%, which need not be done if $KHSO_5$ were the active.

4) All reports explaining existing methods of manufacture, composition, impurities and physical/chemical characteristics, are on the "triple salt" or on stable end-use products containing the triple salt.

5) Once out of the package and dissolved in water prior to use, the various salts hydrolyze upon dissolution and the distinctiveness (identity) of the original ions are lost prior to being used for pesticidal purposes. Therefore, the compounds listed on the registered label do not exist once the product is dissolved prior to use for pesticidal purposes.

6) The presence of the strong oxidizing agent changes the chloride ion in Na Cl to chlorine gas and hypochous acid.

DU PONT CHEMICALS
Chestnut Run Plaza
P.O. Box 80709
Wilmington, DE 19880-0709
Fax (302) 999-4396
Telex 650 339 6061 MCIUW

February 25, 1992

Mr. Richard Otten
Registration and Regulatory Services
5116 Wood Valley Drive
Raleigh, NC 27613

Dear Mr. Otten:

As we discussed, our product Oxone® monopersulfate compound is a peroxygen crystalline powder which is made by partially neutralizing with potassium hydroxide a solution of peroxymonosulfuric acid in sulfuric acid. The crystals which precipitate on neutralization are collected and dried to become the product.

While the product is sometimes stated to have an "active ingredient" of potassium monopersulfate (KHSO5), this is an oversimplification for several reasons:

1. X-Ray data disclosed in the original patents on Oxone® show that the crystals are complex and appear to have the stoichiometry 2KHSO5.KHSO4.K2SO4. Without this crystal mixture, the precipitation of a monoperoxygen product would be difficult if not impossible. [NOTE: Oxone® does not exactly conform to the stated stoichiometry, but is very close to it.]

2. Potassium monopersulfate (KHSO5) is relatively unstable, and probably could not exist in commerce without the potassium bisufate (KHSO4) and potassium sulfate (K2SO4) components.

3. The product Oxone® is invariably dissolved in water at the point of its use. On dissolution, the various ions hydrolyze and separate, and the distinctiveness of the various salts is lost.

21

Because of these reasons, Oxone® should be considered as an entity, with an Active Oxygen content of 4.5% minimum. The designation of potassium monopersulfate as its active ingredient, although occasional useful in explaining the chemistry of the product, is not chemically correct because potassium monopersulfate cannot be separated from Oxone®, nor can it practically be made without the other components.

Regards,

Bruce A. Evans

Bruce A. Evans
Technical Service Consultant

BAE/khl
Enclosure
0225ltr.bae

p. 7 of 32.

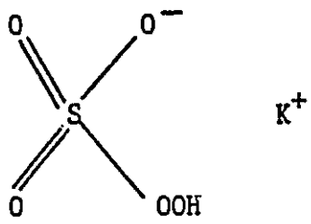
ANTEC VIRKON S

RAW MATERIAL SPECIFICATION

Raw Material: Potassium Monopersulphate / Potassium Hydrogen Sulphate / Potassium Sulphate – Triple Salt.

Synonym : Caroat

Formula : $2KHSO_5 . KHSO_4 . K_2SO_4$



Composition:

$KHSO_5$	45%
$KHSO_4$	25%
K_2SO_4	30%

Appearance: Fine, white powder

Bulk Weight: 1100 - 1200g/l (68-75lb/cu.ft.)

Particle Size:

On 0.8mm	0.1%
On 0.1mm minimum	90%
Through 0.1mm maximum	10%

Active Oxygen Content: 4.5% minimum

pH (1% solution): 2.0 - 3.0

Solubility (20°C): 25g/100ml water

Source: Degussa Ltd
Interox Chemicals Ltd

Dr F M Diffin
Chief Chemist

VIRKON-S

CHEMICAL REACTIONS - PRODUCT CLASSIFICATION

1. The Virkon S system is based on 3 reactions associated with the chemical properties of 3 of its constituents.

POTASSIUM MONO PERSULPHATE - is recognized as a strong oxidizing agent.

It is capable of oxidizing a number of a number of metal ions such as CuI to CuII and FeII to the next higher valency.

It is capable of oxidizing Hydrogen Peroxide to oxygen.

And Chloride ions to elemental Chlorine Gas.

SALT (NaCl) - a carefully controlled quantity is present in Virkon S - and provides the Halide available for oxidation to Chlorine Gas.

The reaction under acid conditions is represented as follows:

$HSO_5 + 2Cl^- + 2H^+ \rightarrow HSO_4 + Cl_2 + H_2O$
(Source Degussa monograph on Caroat).

The Chlorine Gas reacts to form Hypochlorous Acid

$Cl_2 + H_2O \rightleftarrows HOCl + HCl$

The Chlorine Gas and Hypochlorous Acid are in a state of equilibrium.

By limiting the amount of salt present - in Virkon S the amount of Chlorine Gas released at any one time is controlled.

The inclusion of a molar excess of SULFAMIC ACID ensures that the Chlorine produced in solutions of Virkon S at a pH of 2.6 - is not evolved as Gaseous Chlorine.

The reaction follows this path - the Chlorine reacts with the Sulfamic Acid.

$Cl_2 + NH_2 SO_3H \rightarrow NHCl\ SO_3H + HCl$

and subsequently hydrolyses according to this reaction.

$HHClSO_3H + H_2O \rightarrow NH_2\ SO_3H + HOCl$

The HOC1, which is recognized as the active ingredient, reacts with organic matter viruses, bacteria, etc. loses its oxygen and releases the Chlorine ion donated by the Na Cl in the first instance and a chain reaction continues--similar to that described in 'Textile Bleaching' by Marsh.

(Here reference is made to a paper by Kaufemann (BER 1932, 65, 179) and his interpretation of chain reaction in Hypochlorite solutions based on the Haber Will Statter Theory of Chain Reactions).

T. R. Auchincloss, BSc, C Chem, FRSC
Chairman

ANTEC VIRKON S

METHOD OF ANALYSIS

POTASSIUM MONO PERSULPHATE

Principle: Iodine released from an acidic potassium iodide solution by the active oxygen (a) is titrated with sodium thiosulphate to a colourless end point (b):

$$KHSO_5 + 2KI + 2H_2SO_4 \longrightarrow 3KHSO_4 + I_2 + H_2O \quad (a)$$

$$I_2 + 2Na_2S_2O_3 \longrightarrow Na_2S_4O_6 + NaI \quad (b)$$

Reagents: All reagents should be analytical reagent grade. Distilled water and water of equivalent purity, should be used:

Potassium Iodide solution	100G/L
Sodium Thiosulphate solution	0.1N
Sulphuric Acid solution	(1:9)
Starch solution	5G/L

Method:

Weigh accurately about 0.3gm of a sample into a small glass sample cup. Let the weight taken be WG. Add 100ml Sulphuric Acid solution (1:9) into a 250ml conical beaker. Add the glass sample cup and swirl to dissolve the contents. Add 10ml Potassium Iodide solution. Swirl to mix. Immediately titrate with Sodium Thiosulphate (0.1N). Add a few drops of starch solution towards the end of the titration and continue titration to the disappearance of the blue colour. Let the titration be A ml.

Calculation:

Available oxygen content: $\frac{A \times 0.08}{W}$ % wt.

Potassium Permonosulphate content: $\frac{A \times 0.761}{W}$

T R Auchincloss
Chairman

TRA/JB/17.9.86.

CONFIDENTIAL STATEMENT OF FORMULA

Explanation of Certified Limit Settings

Potassium monopersulfate "triple salt" is sold on the basis of a mininum available oxygen content of 4.5% and it is on this level that the Virkon formulation is based. However, in practice the available oxygen content can be as high as 5.1%. In an effort to control the level of this active in Virkon, and to over come the problem of varying available oxygen content, Antec obtains certificates of analysis with each delivery of Triple Salt.

The amount of Triple Salt is then adjusted accordingly. So as not to upset the balance of other ingredients the, amount of Calgon is adjusted (inversely) in line with the Triple Salt correction.

Company Name: A.H. Robins Company
Case Number: 4072
Chemical Name: Potassium peroxymonosulfate

REQUESTS FOR WAIVERS OF CERTAIN TYPE OF DATA

Ecotoxicity and Mammalian Toxicity

Registered uses of potassium peroxymonosulfate present as a "triple salt" are for indoor uses only. There is no exposure of the registered product to terrestrial or aquatic areas. Also, because of the use and handling precautions stated on the label, repeated contact by users is not anticipated.

Therefore, those types of data listed as "CR", Conditional Required, should not be required by EPA to reregister this product; these include:

Guideline Reference Number	Title of Study
71-1(a)	Acute avian oral quail/duck
71-2(a)	Acute avian dietary quail
81-7	Acute delayed neurotox hen
82-3a	90-day feeding rodent
82-1(b)	90-day feeding non-rodent
82-2	21-day dermal rabbit/rat
82-3	90-day dermal rodent
83-4	2-generation repro rat
85-1	General metabolism
85-2	Dermal penetration

New Topic

Reregistration Phase 3 Response
Potassium Peroxymonosulfate

VOLUME 2

PRODUCT CHEMISTRY SUMMARY

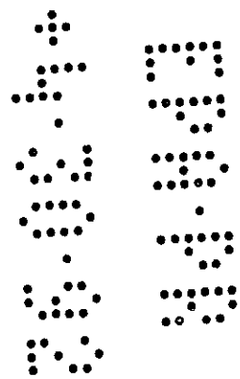
[Divider Page Only -- Not Part of Paginated Report]

New Topic

Reregistration Phase 3 Response
Potassium Peroxymonosulfate

VOLUME 3

DATA SHEET AND MATERIAL SAFETY DATA SHEET
--OXONE® MONOSULFATE--



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DATA SHEET & MATERIAL SAFETY DATA SHEET

OXONE® MONOSULFATE

DATA REQUIREMENT

Guideline No.
63-Series and 81-Series

SOURCE

E. I. du Pont de Nemours & Co. (Inc.)
Wilmington, Delaware 19898

DATE

Data Sheet - Undated
Material Safety Data Sheet - October 1985

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B), or (C).

Company:	A. H. Robins Company
Company Agent:	Dr. Donald L. Gilbert
Title:	Regulatory Affairs and Product Development Special Products Division
Signature:	Donald L. Gilbert
Date:	April 28, 92

GOOD LABORATORY PRACTICE STATEMENT

This study was performed and reported prior to the effective date of the Good Laboratory Requirements as stated in 40 CFR Part 160.

Submitter of Study: Donald L. Gilbert

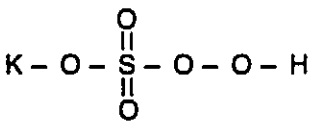
Dr. Donald L. Gilbert
Regulatory Affairs and Product Development
A. H. Robins Company

Date: April 28, 92

OXONE® Monopersulfate Compound

*OXONE** Monopersulfate Compound is a white, granular, free-flowing powder which is of interest in applications which require a strong, odorless oxidant. It is a peroxygen compound that is especially useful in formulated specialty products such as denture cleaners, swimming pool products, laundry bleaches, scouring powders and bowl cleaners. *OXONE* is also used as a selective oxidant in the manufacture of organic chemicals.

OXONE is a triple salt with the formula $2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$. The active component, potassium monopersulfate, has the chemical structure



The physical properties and typical analyses of *OXONE* are shown in Table I.

TABLE I
DU PONT *OXONE*® PHYSICAL PROPERTIES AND TYPICAL ANALYSES*

Molecular Weight	614.7
Active Oxygen, % min.	4.5
% average analysis	4.7
% theoretical (triple salt)	5.2
Active Component ($KHSO_5$) % min.	42.8
Bulk Density, g/cm³ (Mg/m³)	1.12-1.20
lb/ft³	70-75
Particle Size through USS #20 Sieve, %	100
through USS #200 Sieve, % max. (also see Table III)	10
pH @ 25 C (77 F)	
1% solution	2.3
3% solution	2.0
Solubility g/100 g H_2O, 20C (68F) (also see Table II)	25.6
Moisture Content, %	0.1
Stability, % active oxygen loss/month	<1
Standard Electrode Potential (E°), volts	−1.44
Heat of Decomposition kJ/kg	251
Btu/lb	108
Thermal Conductivity, W/m•K	0.161
Btu•ft/h•ft²•F	0.093

*This table gives typical properties based on historical production performance. Du Pont does not make any express or implied warranty that this product will continue to have these typical properties.

Solubility

OXONE is very soluble in water as shown in Table II. This excellent solubility offers a distinct advantage over less soluble dry oxidants, such as sodium perborate, particularly at relatively low temperatures. At 20 C, the solubility of *OXONE* in water is greater than 25 weight percent.

Water-ethanol, water-acetic acid, and water-ethanol-acetic acid mixtures have been used successfully when solvents other than 100% water were desired.

*Reg. U.S. Pat. and Tm. Off., Du Pont Company. *OXONE*® Monopersulfate Compound is made only by Du Pont.

NOTICE: *OXONE*® MONOPERSULFATE COMPOUND CAUSES IRRITATION.
See Personal Safety and First Aid on page 3.

TABLE II

SOLUBILITY OF *OXONE*® MONOPERSULFATE COMPOUND IN WATER

Temperature C	Temperature F	g *OXONE*®/100 g H_2O
20	68	25.6
27	80	26.8
49	120	30.0
60	140	31.5
71	160	33.5

TABLE III

TYPICAL PARTICLE SIZE ANALYSIS OF DU PONT OXONE® MONOPERSULFATE COMPOUND

US SCREEN SIZE (Mesh)	APPROX. WEIGHT % ON SCREEN, CUMULATIVE
30	1
70	68
100	84
200	98
325	100

Stability

Temperature and pH can affect the stability of solutions of *OXONE* monopersulfate compound (Figures 1 and 2).

At pH values below 6 and at 12, solutions of *OXONE* are relatively stable; however, at pH 9 a point of minimum stability exists. At pH 7.5 or lower, active oxygen exists as HSO_5^-, while at pH 12 the active oxygen species is $SO_5^=$. Between pH 7.5 and 12 both ionic species exist in solution and minimum stability corresponds to equal concentrations of HSO_5^- and $SO_5^=$.

OXONE solutions are not as sensitive to trace metal impurities as most peroxygen compounds. However, cobalt, nickel, copper, and manganese ions do catalyze the decomposition of *OXONE* with the evolution of oxygen gas.

CHEMICAL PROPERTIES

Oxidation Potential

The standard electrode potential (E°) of *OXONE* is −1.44 volts for the reaction:

$$HSO_4^- + H_2O \longrightarrow HSO_5^- + 2H^+ + 2e^-$$

This high potential suggests many room temperature oxidations with *OXONE*: halide ion to halogen, ferrous ion to ferric, manganous ion to manganic, and hydrogen peroxide to oxygen.

Formulation

OXONE is compatible with anhydrous salts such as sodium sulfate, sodium tripolyphosphate, tetrasodium pyrophosphate, sodium carbonate, and sodium metasilicate. Conventional surfactants such as alkyl aryl sulfonates and limited quantities of nonionic detergents may also be used in formulations of *OXONE*.

FIGURE 1

STABILITY OF A 1% SOLUTION OF *OXONE*®, AT VARIOUS TEMPERATURES

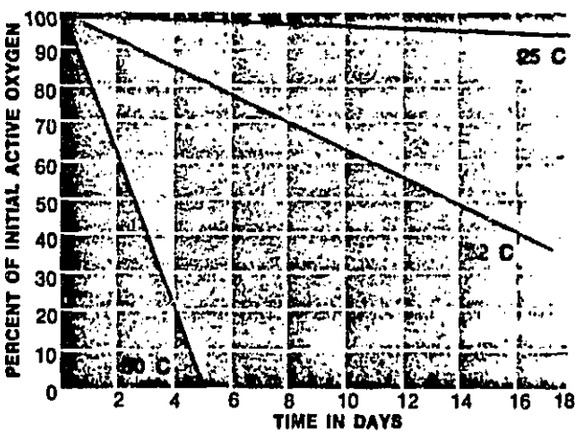
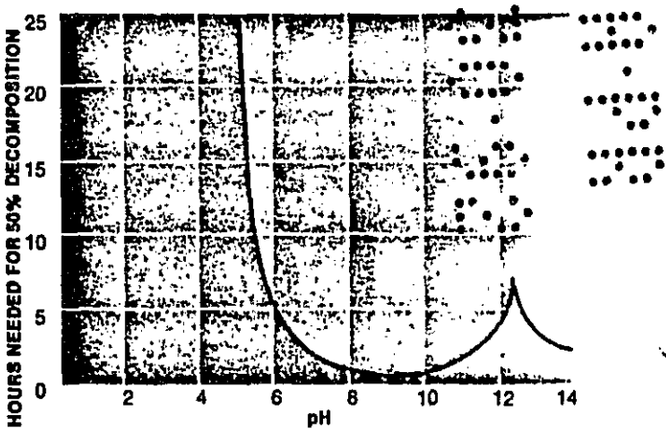


FIGURE 2

EFFECT OF pH* ON STABILITY OF A 3% SOLUTION OF *OXONE*® AT 32 C (89.6 F)



*pH adjusted with KOH.

CHEMICAL REACTIONS

OXONE® monopersulfate compound reacts with many organic compounds in aqueous or solvent-water solutions to convert:

1. Phenol to quinone (Elbs persulfate oxidation).
2. Cyclic ketones to lactones.
3. Toluene to benzoic acid.
4. Diphenylmethane to benzophenone.

OXONE can convert:

1. Olefins to glycols or glycol esters, depending upon the solvent system selected.
2. Cyclohexene to trans- rather than cis-cyclohexanediol.
3. Primary aryl amines to nitroso compounds.
4. Pyridine to pyridine-N-oxide by a slurry of *OXONE* in glacial acetic acid.

Epoxides have not been isolated from reaction systems of *OXONE* and olefins.

OXONE can initiate the free radical polymerization of typical vinyl monomers such as vinyl acetate, ethyl acrylate and acrylonitrile.

An atypical reaction is the conversion of toluene to benzyl halide by heating with a dry mixture of *OXONE* and sodium chloride or sodium bromide.

Detailed information on the use of *OXONE* in organic reactions appears in "Oxidation of Organic Substances by Potassium Peroxymonosulfate" by R. J. Kennedy & A. M. Stock, J. Org. Chem., 25, 1901 (1960).

PERSONAL SAFETY AND FIRST AID

OXONE monopersulfate compound has a low order of toxicity when taken internally. The approximate lethal dose (ALD) for rats is 2250 mg/kg.

OXONE is irritating due to its acidity and oxidizing properties. Du Pont observes an airborne exposure limit to *OXONE* dust of 1 mg/m³, 8-hour time weighted average.

Safety Precautions

Persons handling *OXONE* should avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly after handling and launder contaminated clothing before reuse. Exposure can be minimized by providing adequate ventilation and by wearing rubber or plastic-coated gloves and chemical safety goggles when handling *OXONE*.

Site Facilities

The following safety equipment should be easily accessible in all areas where *OXONE* is handled or stored:

Safety Showers with quick opening valves which stay open. Water should be supplied through insulated lines.

Water Hydrant and Hose or other means of flushing spills with large volumes of water under low pressure.

Eye Wash Fountains or other means for washing the eyes with a gentle flow of tap water.

First Aid

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. Flush skin with water. If inhaled, remove to fresh air.

APPLICATIONS

Laundry Bleach

OXONE monopersulfate compound can be readily formulated with conventional anhydrous alkaline fillers into a stable, free-flowing, dry bleach. In formulating a dry bleach with *OXONE*, sufficient alkali must be used to insure a pH of 9-10 in the laundry use. A suggested mixture of 35% *OXONE* and 65% light granular soda ash is simple, low cost, with low bulk density and has an attractive appearance. In use, a concentration of at least 25 ppm of active oxygen is preferable in the laundry solution (approximately 4 ounces of the 35/65 mixture per 18 gallons of water will yield 25 ppm active oxygen.) For stain removal, concentrations of 200 ppm active oxygen in hot water may be used.

Denture Cleaners

The high oxidation potential of *OXONE* suggests its application in various cleaning compounds where it is desired to eliminate oxidizable discolorations.

Since *OXONE* is acidic, it is usually buffered to near neutral or alkaline pH when compounded into cleansers. The properties of *OXONE* have been shown to be particularly adaptable to denture cleaner formulations because of its ability to decolorize food and other organic stains.

To obtain the desired pH and cleansing properties, a general purpose denture cleaner formulation may contain 20-25% *OXONE* and some of the following: sodium perborate monohydrate, diethylenetriamine pentaacetic acid (DTPA), tetrasodium pyrophosphate, sodium

tripolyphosphate, sodium metasilicate, sodium carbonate, sodium bicarbonate, sodium sesquicarbonate, citric acid, tartaric acid, wetting agent or detergent, sodium sulfate, sodium chloride, and fragrance.

The above additives must be anhydrous, otherwise, undesirable reactions will occur between the acidic solution of *OXONE*® and the alkaline additives.

SWIMMING POOL/SPA PRODUCTS

Swimming Pool/Spa Oxidizer ("Shocking Agent") – *OXONE* monopersulfate compound can be used as an auxiliary oxidant ("shocking agent") in swimming pools and spas for the purpose of reducing the organic content of the water. The treatment, which is generally recommended at two-week intervals or whenever cloudiness is present, increases the clarity of the water and reduces eye burn and "chlorine" odor by destroying chloramines.

The excellent solubility of *OXONE* makes it ideal for addition to pools and spas by broadcast or via the filter basket.

Unlike chlorine-based shocking agents which superchlorinate the pool, *OXONE* does not significantly increase the chlorine level. Therefore the pool need not be closed except for a short period to fully circulate the *OXONE*.

In this application, *OXONE* is not a disinfectant and must be used *in addition* to an EPA (FIFRA) registered disinfectant.

***OXONE*/Sodium Bromide Disinfection** – *OXONE* can also be used as one part of a two-part disinfectant system for spas and hot tubs with sodium bromide. *OXONE* oxidizes bromide to bromine, which is present as the active disinfectant HOBr in the pH range usually found in spas and hot tubs. This two-part disinfectant system has been EPA (FIFRA) registered by several manufacturers of swimming pool chemicals; such registration is necessary before offering disinfectants for sale in the United States. Other jurisdictions may also require additional registrations.

Since the organic loading of a spa or hot tub is often greater than that of a swimming pool, chlorine-based disinfectants have a tendency to cause cloudiness and chlorine odor because of the formation of stable chloramines. Bromine-based disinfectants form bromamines, which are unstable and are recognized as good disinfectants. Bromine-disinfected spas have lower odor, less cloudiness, and cause less eye irritation than chlorine-disinfected spas.

For this use, it may be desirable to neutralize the acidity of *OXONE* by formulation with an anhydrous alkaline salt such as sodium carbonate. Dilution to control dosage may be done with anhydrous sodium sulfate.

Bowl Cleaners

Toilet bowl cleaners for home use are composed primarily of sodium bisulfate with small amounts of detergent, fragrance, and corrosion inhibitor. The solution pH of these cleaners in use is 1-2. Functions of the acidic bowl cleaners are soil and stain removal. These product characteristics may be enhanced by including 1-3% *OXONE* in bowl cleaner formulation.

TEST METHODS

Active Oxygen/Active Component

The active oxygen in *OXONE* monopersulfate compound or in mixtures of *OXONE* with other materials can be determined by using the standard iodometric titration. Iodine released from an acidic potassium iodide solution by the active oxygen in *OXONE* is titrated with standard sodium thiosulfate to a colorless endpoint. The following method is suggested.

1. Take four samples, one from each quarter of the material to be analyzed.
2. Blend samples by using a small blender or rolling in a container for about 5 minutes.
3. Empty the blended sample onto a glass pie plate or flat dish and take small samples at random to obtain 0.5 g for analysis.
4. Weigh the sample to the nearest 0.001 g.
5. In a 250-mL beaker equipped with stirrer add 50 mL distilled water, 5 mL of 20% sulfuric acid, and 10 mL 20% potassium iodide solution. Then add the weighed sample, and stir to completely dissolve it.
6. Titrate with 0.1 N sodium thiosulfate solution to a colorless endpoint that persists for 30 seconds. (Starch indicator should be used for enhancement of the end point.)
7. Calculate:

$$\% \text{ active oxygen} = \frac{\text{mL thiosulfate} \times N \times 0.008 \times 100}{\text{sample weight (grams)}}$$

where N is the normality of the sodium thiosulfate.

$$\% \text{ active component } (KHSO_5) = \frac{\% \text{ active oxygen}}{0.1053}$$

Moisture Content

1. Using the sampling procedure above, weigh 10 g (±0.01 g) in a tared aluminum dish.
2. Dry for 30 min. in a 65 C ± 0.5 C oven.
3. Cool in a desiccator and weigh.
4. Calculate the percent moisture:

$$\% \text{ moisture} = \frac{\text{original wt.} - \text{dry wt.}}{\text{original wt.}} \times 100$$

SHIPPING CONTAINERS

A moisture barrier package is recommended for formulated mixtures of *OXONE*®. Du Pont ships *OXONE* in multiwalled, moisture-resistant, 25-kg (55.1 lb) net paper bags. *OXONE* Monopersulfate Compound is not regulated as a hazardous material by the Department of Transportation as of December, 1984*.

STORAGE & HANDLING

Precautions in Use

OXONE Monopersulfate Compound is a moderately strong oxidizer. It should be stored in a cool, dry location away from combustible materials.

Like all other peroxygen compounds *OXONE* undergoes very slow decomposition in storage, which also liberates heat. In order to provide sufficient surface area to dissipate the small amount of heat generated, *OXONE* should not be stored or processed in large masses exceeding a cube 4 ft on each side (64 ft^3) or approximately 4500 lb *OXONE*. Storage of quantities of *OXONE* in excess of this limit can lead to runaway decomposition with liberation of large amounts of heat and oxygen gas.

If the internal temperature of the material exceeds 300 C (m.p. K_2SO_4) the material may fuse, and could generate SO_2 or SO_3 gases.

Pallets of *OXONE* (less than 64 ft^3/pallet) can be stacked if there are 2-3 inches of air space between pallets.

Grinding or intensive mixing may generate sufficient heat to fuse *OXONE* and cause the ignition of oxidizable material present.

Spills

Spills and sweepings should be removed and the area thoroughly washed with water.

Dry Stability

When stored in a cool, dry place, *OXONE* is an exceptionally stable peroxygen compound. The rate of decomposition at these storage conditions should be less than 1% per month of contained active oxygen.

Materials of Construction

The primary consideration in choosing equipment for handling *OXONE* and solutions of *OXONE* is to prevent contamination of the product with rust or other catalytic metals. Thus, stainless steel, porcelain, glass and many plastics may be considered suitable. Containers and small packages for *OXONE* should be of moisture barrier construction.

The use of *OXONE* and sodium chloride in formulations may cause mild corrosion problems, but the use of sodium nitrate or other chloride corrosion inhibitors will minimize this problem.

*Due to changing governmental regulations such as those of the Department of Transportation, Department of Labor, U.S. Environmental Protection Agency and the Food and Drug Administration, references herein may be superseded. The user should consult and follow the current governmental regulations, such as Hazard Classification, Labeling, Food Use Clearances, Worker Exposure Limitations and Waste Disposal Procedures for the product described in this literature.

E. I. du Pont de Nemours & Co. (Inc.)
Wilmington, Delaware 19898

U.S. Sales and Services

For placing orders or requesting additional product information, please use our convenient 24-hour toll-free telephone number. If you prefer, you can write to us.

By Phone

Toll free in continental U.S. (except Delaware)
(800) 441-9442

In Delaware
(302) 774-2099

By Mail

E. I. du Pont de Nemours & Co. (Inc.)
Chemicals and Pigments Dept.
Customer Service Center
Wilmington, DE 19898

International Sales Offices

CANADA
Du Pont Canada Inc.
Box 660
Montreal S, P.Q. H3C 2V1
(514) 861-3861

Du Pont Canada Inc
P.O. Box 2300
Streetsville Postal Station
Mississauga, Ontario L5M 2J4
(416) 821-5570

LATIN AMERICA
E. I. du Pont de Nemours & Co. (Inc.)
Chemicals and Pigments Dept.
Latin America Sales Office
Brandywine Building
Wilmington, DE 19898
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CH-1211
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022-378111

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Minato-ku
Tokyo 107, Japan
585-5511

Du Pont Far East, Inc.
Maxwell Road
P.O. Box 3140
Singapore 9051
273-2244

DUPONT
REG US PAT & TM OFF

DU PONT

MATERIAL SAFETY DATA SHEET

IDENTIFICATION

NAME
Oxone* Monopersulfate Compound

GRADE
Technical

SYNONYMS
Potassium Peroxymonosulfate

ID. NOS./CODES
Du Pont Code No: DP6-56-8

MANUFACTURER/DISTRIBUTOR
E. I. du Pont de Nemours & Co. (Inc.)

ADDRESS
Wilmington, DE 19898

CHEMICAL FAMILY
Peroxygen Salt

FORMULA
$2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$

PRODUCT INFORMATION PHONE
(800) 441-9442

MEDICAL EMERGENCY PHONE
(800) 441-3637

TRANSPORTATION EMERGENCY PHONE
CHEMTREC (800) 424-9300

PHYSICAL DATA

BOILING POINT, 760 mm Hg
Decomposes

SPECIFIC GRAVITY
1.1 to 1.4

VAPOR DENSITY
Not volatile

pH INFORMATION
1% solution = 2.3;
3% solution = 2.0

FORM
Solid

COLOR
White

MELTING POINT
Decomposes

VAPOR PRESSURE
Nil

SOLUBILITY IN WATER
25.6% at 20°C (68°F)

EVAPORATION RATE (BUTYL ACETATE=1)
Not volatile

APPEARANCE
Granular; free flowing

ODOR
Odorless

*Reg. U.S. Pat. & Tm. Off., Du Pont Company. Oxone® Monopersulfate Compound is made only by Du Pont.

HAZARDOUS COMPONENTS

MATERIAL(S)	APPROXIMATE %
$2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$	86-92

HAZARDOUS REACTIVITY

INSTABILITY
Stable

INCOMPATIBILITY
The mixture of Oxone® with compounds containing halides or active halogens can cause release of the respective halogen if moisture is present. For example, mixture with sodium dichloroisocyanuride or with sodium chloride can cause release of chlorine gas; mixture with cyanides can cause release of hydrogen cyanide gas; and heavy metal salts such as those of cobalt, nickel, copper, or manganese cause the evolution of oxygen.

DECOMPOSITION
Releases oxygen gas

POLYMERIZATION
Will no occur.

FIRE AND EXPLOSION DATA

FLASH POINT Will not burn

FLAMMABLE LIMITS IN AIR, % BY VOL.
LOWER Not applicable
UPPER Not applicable

AUTOIGNITION TEMPERATURE
Not applicable

FIRE AND EXPLOSION HAZARDS
Storage of large masses of Oxone® can trap heat and lead to ignition of paper bags. Grinding or intensive mixing may cause ignition of oxidizable material present.

EXTINGUISHING MEDIA Water

SPECIAL FIRE FIGHTING INSTRUCTIONS None

HEALTH HAZARD INFORMATION

PRINCIPAL HEALTH HAZARDS (Including Significant Routes, Effects, Symptoms of Over-Exposure, and Medical Conditions Aggravated by Exposure)

Causes irritation.

Inhalation 4-hour LC50: >5 mg/L in rats
Oral LD50: 2250-9500 mg/kg in rats

The compound is a strong eye and skin irritant. Toxic effects described in animals from short exposures include irritation or corrosion of mucosal surfaces. Tests in bacterial or mammalian cell cultures demonstrate no mutagenic activity.

Human health effects of overexposure may initially include: skin irritation with discomfort or rash; eye irritation with discomfort, tearing, or blurring of vision; or irritation of the upper respiratory passages.

CARCINOGENICITY
Not listed as a carcinogen by IARC, NTP, OSHA, ACGIH or Du Pont.

EXPOSURE LIMITS (PEL (OSHA), TLV (ACGIH), AEL (DU PONT), ETC.)
Exposure limits for Oxone® Monopersulfate Compound have not been established by OSHA or ACGIH. Du Pont has elected to observe an 8-hour TWA airborne exposure limit of 1 mg/m^3.

SAFETY PRECAUTIONS
Avoid contact with eyes, skin, and clothing.
Avoid breathing dust.
Wash throughly after handling.

FIRST AID
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. Flush skin with water. Wash clothing before reuse.

If swallowed, do not induce vomiting. Give large quantities of water. Call a physician. Never give anything by mouth to an unconscious person.

PROTECTION INFORMATION

GENERALLY APPLICABLE CONTROL MEASURES
Good general ventilation should be provided to keep vapor concentrations below the flammability and exposure limits.

PERSONAL PROTECTIVE EQUIPMENT
Chemical splash goggles and leather gloves. If exposure limit is exceeded, wear OSHA-permissable particulate removing (dust-filter) respiratory protection.

DISPOSAL INFORMATION

SPILL, LEAK OR RELEASE
Sweep up. Flush area with low pressure water.

WASTE DISPOSAL
Comply with Federal, State, and local regulations. If approved, flush to sewer to waste treatment plant. Large quantities should be neutralized with soda ash.

SHIPPING INFORMATION

DOT (172.101)

PROPER SHIPPING NAME
Not regulated as a hazardous material.

HAZARD CLASS Not regulated

DOT/IMO (172.102)

PROPER SHIPPING NAME
Not regulated as a hazardous material.

HAZARD CLASS Not regulated

IMO

PROPER SHIPPING NAME
Not regulated as a hazarous material.

HAZARD CLASS Not regulated

IATA/ICAO

PROPER SHIPPING NAME
Not regulated as a hazardous material.

HAZARD CLASS Not regulated

OTHER INFORMATION

SHIPPING CONTAINERS Multiwall bags

STORAGE CONDITIONS
Store in a cool, dry, well-ventilated area. Stack on pallets providing air space; closely stacked bags should not exceed a 4-ft. (1.2m) cube. Keep packages dry. Do not store with combustible materials..

ADDITIONAL INFORMATION AND REFERENCES

For further information, see Du Pont "Oxone® Monopersulfate Compound" Data Sheet.

DATE OF LATEST REVISION/REVIEW: 8/85
PERSON RESPONSIBLE FOR MSDS: J. C. Watts, Du Pont Co., C&P Dept., Chestnut Run, Wilmington, DE 19898, (302) 999-4946

DUPONT

New Topic

Reregistration Phase 3 Response
Potassium Peroxymonosulfate

VOLUME 4

ACUTE TOXICITY SUMMARY & DATA GUIDELINE STUDIES

[Divider Page Only -- Not Part of Paginated Report]

ACUTE TOXICITY SUMMARIES
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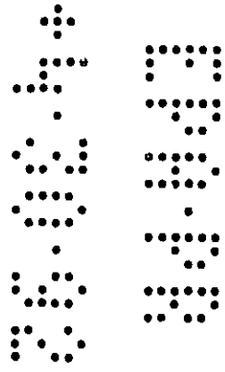

[Divider Page Only – Not Part of Paginated Report]

New Topic

94340
chemical = 063604
company = 000778
case = 4072

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

10/22/92

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear Phase 3 Submitter:

Your Reregistration Phase 3 submission captioned above has been screened for compliance with PR Notice 89-3, and has been found unacceptable for further review. The rejected documents are being returned to you for correction.

A deficiency listing is attached, in the same sequence as the Phase 3 worksheet. It shows why each rejected document was unacceptable.

If you have any questions about the basis for these rejections, or about what you must do to make these documents acceptable, please call me at (703) 305-5363.

When you resubmit, identify your resubmission clearly as a "Phase 3 Resubmission" and submit it by mail to:

Attn: Teresa Downs, Mail Code H7502C
Reregistration Phase 3 Response
US EPA: Office of Pesticide Programs
401 M Street, SW
Washington, DC 20460

or by private courier or express company to:

Attn: Teresa Downs, Mail Code H7502C
Reregistration Phase 3 Response
Document Processing Desk, Rm. 266A
1921 Jefferson Davis Highway, Crystal Mall 2
Arlington, VA 22202

Sincerely,

John M. Carley, Manager
Phase 3 In-Processing

Attachment

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Phase 3 Deficiency Listing - Page 1

Company (000778): A.H. ROBINS CO.
Chemical (063604): Potassium peroxymonosulfate

Guideline/ Crop	Cld MRID	S/R	Deficiencies Noted
61-1	40581501	S	Page 4 of each summary must bear a Certification of Access to Raw Data, using the mandatory language specified in section VIII(D) of PR Notice 89-3.
61-2(a)	40581501	S	
61-2(b)	40581501	S	Page 4 of each summary must bear one of the two alternative standard forms of the Certification of Accuracy of Summary and Adequacy of Study defined in section VIII(E) of PR Notice 89-3.
62-1	40581502	S	
62-2	40581502	S	Each passage of confidential information removed to the confidential attachment must be cross-referenced to and from the location in the parent summary from which it was removed. Cross references are not accurate.
62-3	40581502	S	
63-2	40581503	S	
63-3	40581503	S	
63-4	40581503	S	
63-5	40581503	S	
63-6	40581503	S	
63-7	40581503	S	
63-8	40581503	S	
63-12	40581503	S	

Phase 3 Deficiency Listing - Page 2

Company (000778): A.H. ROBINS CO.
Chemical (063604): Potassium peroxymonosulfate

Guideline/ Crop	Old MRID	S/R	Deficiencies Noted
63-13	40581503	S	
63-17	40581503	S	
63-20	40581503	S	
171-2	40581501	S	
81-1		S	The old MRID cited in column 5 is invalid. You must determine the valid MRID for the previously submitted study you are citing. *
			Page 2 of each Phase 3 summary must bear one of the two standard statements of data confidentiality claims defined in section VI(D) (2) and Attachment 3 of PR Notice 86-5.
			Page 3 of each summary must bear an appropriate statement concerning the compliance or noncompliance of the original study with EPA's Good Laboratory Practices regulations. See CFR 160.12.
			Page 4 of each summary must bear a Certification of Access to Raw Data, using the mandatory language specified in section VIII(D) of PR Notice 89-3.
			Page 4 of each summary must bear one of the two alternative standard forms of the Certification of Accuracy of Summary and Adequacy of Study defined in section VIII(E) of PR Notice 89-3.
81-2		S	The old MRID cited in column 5 is

* For toxicity documents with no known MRID, it is recommended that you submit 3 copies of the original study to the Document Processing Desk, EPA, OPP.

Guideline/ Crop	Old MRID	S/R	Deficiencies Noted
			invalid. You must determine the valid MRID for the previously submitted study you are citing. Page 2 of each Phase 3 summary must bear one of the two standard statements of data confidentiality claims defined in section VI(D) (2) and Attachment 3 of PR Notice 86-5. Page 3 of each summary must bear an appropriate statement concerning the compliance or noncompliance of the original study with EPA's Good Laboratory Practices regulations. See CFR 160.12. Page 4 of each summary must bear a Certification of Access to Raw Data, using the mandatory language specified in section VIII(D) of PR Notice 89-3. Page 4 of each summary must bear one of the two alternative standard forms of the Certification of Accuracy of Summary and Adequacy of Study defined in section VIII(E) of PR Notice 89-3.
81-3	00138805	S	Page 2 of each Phase 3 summary must bear one of the two standard statements of data confidentiality claims defined in section VI(D) (2) and Attachment 3 of PR Notice 86-5. Page 3 of each summary must bear an appropriate statement concerning the compliance or noncompliance of the original study with EPA's Good Laboratory Practices regulations. See CFR 160.12. Page 4 of each summary must bear a
81-3	00138806	S	

Phase 3 Deficiency Listing - Page 4

Company (000778): A.H. ROBINS CO.
Chemical (063604): Potassium peroxymonosulfate

Guideline/ Crop	Old MRID	S/R	Deficiencies Noted
			Certification of Access to Raw Data, using the mandatory language specified in section VIII(D) of PR Notice 89-3. Page 4 of each summary must bear one of the two alternative standard forms of the Certification of Accuracy of Summary and Adequacy of Study defined in section VIII(E) of PR Notice 89-3.
81-4		S	The old MRID cited in column 5 is invalid. You must determine the valid MRID for the previously submitted study you are citing. Page 2 of each Phase 3 summary must bear one of the two standard statements of data confidentiality claims defined in section VI(D) (2) and Attachment 3 of PR Notice 86-5. Page 3 of each summary must bear an appropriate statement concerning the compliance or noncompliance of the original study with EPA's Good Laboratory Practices regulations. See CFR 160.12. Page 4 of each summary must bear a Certification of Access to Raw Data, using the mandatory language specified in section VIII(D) of PR Notice 89-3. Page 4 of each summary must bear one of the two alternative standard forms of the Certification of Accuracy of Summary and Adequacy of Study defined in section VIII(E) of PR Notice 89-3.
81-5		S	The old MRID cited in column 5 is

Company (000778): A.H. ROBINS CO.
Chemical (063604): Potassium peroxymonosulfate

Guideline/ Crop	Old MRID	S/R	Deficiencies Noted
			invalid. You must determine the valid MRID for the previously submitted study you are citing. Page 2 of each Phase 3 summary must bear one of the two standard statements of data confidentiality claims defined in section VI(D) (2) and Attachment 3 of PR Notice 86-5. Page 3 of each summary must bear an appropriate statement concerning the compliance or noncompliance of the original study with EPA's Good Laboratory Practices regulations. See CFR 160.12. Page 4 of each summary must bear a Certification of Access to Raw Data, using the mandatory language specified in section VIII(D) of PR Notice 89-3. Page 4 of each summary must bear one of the two alternative standard forms of the Certification of Accuracy of Summary and Adequacy of Study defined in section VIII(E) of PR Notice 89-3.
81-6		S	The old MRID cited in column 5 is invalid. You must determine the valid MRID for the previously submitted study you are citing. Page 2 of each Phase 3 summary must bear one of the two standard statements of data confidentiality claims defined in section VI(D) (2) and Attachment 3 of PR Notice 86-5. Page 3 of each summary must bear an appropriate statement concerning the

Phase 3 Deficiency Listing - Page 6

Company (000778): A.H. ROBINS CO.
Chemical (063604): Potassium peroxymonosulfate

Guideline/ Crop	Old MRID	S/R	Deficiencies Noted
			compliance or noncompliance of the original study with EPA's Good Laboratory Practices regulations. See CFR 160.12. Page 4 of each summary must bear a Certification of Access to Raw Data, using the mandatory language specified in section VIII(D) of PR Notice 89-3. Page 4 of each summary must bear one of the two alternative standard forms of the Certification of Accuracy of Summary and Adequacy of Study defined in section VIII(E) of PR Notice 89-3.
84-2(a)		S	We did not find the summary associated with this MRID in your submission.